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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,995	03/23/2004	Marwan Abboud	21819-194U	2340
31292	7590	12/27/2005	EXAMINER	
CHRISTOPHER & WEISBERG, P.A. 200 EAST LAS OLAS BOULEVARD SUITE 2040 FORT LAUDERDALE, FL 33301			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/806,995

Applicant(s)

ABBOUD ET AL.

Examiner

Alex B. Toy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 12-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/6/04; 9/14/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 12-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 8, 2005.

Applicant's election without traverse of Species I is acknowledged. Regarding the election of species, the examiner revises Species I to include the embodiments shown in Figs. 1A and 1B. However, claims 7 and 8 (which depends from claim 7) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Species VII-XIII shown in Figs. 2C-2D, there being no allowable generic or linking claim.

In summary, claims 7-8 and 12-31 are withdrawn from further consideration. Claims 1-6 and 9-11 are examined.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fram (U.S. Pat. No. 5,540,679).

Regarding claim 1, Fram discloses a method of inflating and deflating a catheter having an expandable membrane, the method comprising the steps of:

controllably inflating the expandable membrane to a target pressure or volume (col. 5, ln. 64-67 and Fig. 6);

ablating a desired tissue region while maintaining the target pressure or volume of the expandable membrane (col. 1, ln. 45-46, col. 5, ln. 64-67, and col. 6, ln. 4-6);

and controllably deflating the expandable membrane (col. 5, ln. 11-17).

Regarding claim 10, Fram discloses method of claim 1, wherein the step of ablating the desired tissue region is part of a radio frequency ablation process (col. 5, ln. 26-27).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3739

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679).

Regarding claim 2, Fram discloses method of claim 1. In addition, Fram discloses heating the balloon up to a preset temperature and deactivating the heating process at any desired time (col. 7, ln. 45-49). Therefore, as a matter of routine skill in the art, it would have been obvious to have kept the expandable membrane inflated until a region proximate the expandable membrane reached a predetermined temperature range and then deflated the balloon once that preset temperature was reached in order to remove the balloon once the procedure was completed.

Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Yamaguchi (U.S. Pat. No. 5,433,740).

Regarding claims 3, Fram discloses method of claim 1. The claim differs from Fram in calling for the inflation/deflation control means to be located within a first console. Yamaguchi, however, teaches a control means 18 located within a first console

Art Unit: 3739

1 for inflating and deflating a balloon 6 (col. 4, ln. 47-64 and Figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have located the inflation/deflation control means within a first console in view of the teaching of Yamaguchi as an obvious alternate means of better controlling the inflation and deflation of a balloon catheter that is known in the art.

Regarding claim 6, Fram discloses method of claim 1. The claim differs from Fram in calling for the method of if the target pressure or volume is not reached, re-inflating the expandable membrane in order to reach the target pressure or volume. Yamaguchi, however, teaches adjusting fluid flow in order to reach the target pressure or volume in order to keep the balloon in intimate contact with the cavity wall and detect leaks (col. 4, ln. 54-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of claim 6 in the method of Fram in view of the teaching of Yamaguchi in order to keep the balloon in intimate contact with the cavity wall and detect leaks.

Regarding claim 11, Fram discloses a method for inflating and deflating a catheter having an expandable membrane, the catheter being part of a catheter system including a first console (see rejection of claim 3), a catheter, and an umbilical system coupling the first console to the catheter (see rejection of claim 3), the method comprising the steps of:

controllably inflating the expandable membrane proximate a desired tissue region, the expandable membrane being inflated to a target pressure or volume in order to provide sufficient mechanical force against the desired tissue region (Fig. 10);

ablating the desired tissue region while maintaining the expandable membrane at the target pressure or volume (col. 1, ln. 45-46, col. 5, ln. 64-67, and col. 6, ln. 4-6); and controllably deflating the expandable membrane (col. 5, ln. 11-17).

The claim differs from Fram in calling for the method to further comprise evacuating air from the expandable membrane by creating a vacuum in the expandable membrane. Yamaguchi, however, teaches evacuating air from the expandable membrane by creating a vacuum in the expandable membrane (col. 6, ln. 47-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of evacuating air in the method of Fram in view of the teaching of Yamaguchi in order to remove unwanted air from the balloon.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Yamaguchi ('740) and further in view of Edwards (U.S. Pat. No. 6,258,087 B1).

Regarding claim 4, Fram discloses the method of claims 1 and 3 in view of Yamaguchi. The claim differs from Fram in view of Yamaguchi in calling for the inflation/deflation control means to be a Proportional Integral Derivative controller. Edwards, however, teaches a pump system that uses a Proportional Integral Derivative controller to control fluid flow (col. 36, ln. 15-20) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a Proportional Integral Derivative controller in the method of Fram in view of Yamaguchi,

Art Unit: 3739

further in view of the teaching of Edwards as an obvious means of better controlling fluid flow to the balloon that is known in the art.

Regarding claim 5, Fram/Yamaguchi/Edwards disclose the method of claims 1, 3, and 4. In addition, the inflation/deflation control means of Yamaguchi includes a pressure switch that controls an on/off valve.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Joye (US PGPub 2002/0045894 A1).

Regarding claim 9, Fram discloses the method of claim 1. The claim differs from Fram in calling for the step of ablating the desired tissue region to be part of a cryoablation process. Joye, however, teaches a balloon catheter for cryoablation (pg. 1, ¶ 3 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have introduced cryogenic fluid into the balloon of Fram in view of the teaching of Joye as an obvious alternate method of using a balloon catheter to treat tissue that is well-known in the art.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 3125096 A	USPAT	Antiles et al.
US 4955377 A	USPAT	Lennox; Charles D. et al.
US 5190540 A	USPAT	Lee; Benjamin I.
US 5300099 A	USPAT	Rudie; Eric N.
US 5405346 A	USPAT	Grundy; David A. et al.
US 5433708 A	USPAT	Nichols; Colin J. et al.



Art Unit: 3739

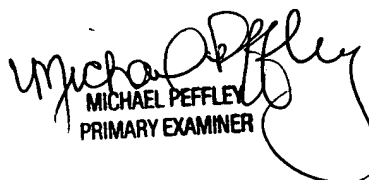
US 5624392 A	USPAT	Saab; Mark A.
US 5957962 A	USPAT	Wallsten; Hans I et al.
US 6004269 A	USPAT	Crowley; Robert J. et al.
US 6283959 B1	USPAT	Lalonde; Jean Pierre et al.
US 20040002748 A1	US-PGPUB	Ryan, Thomas P. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT  
12/22/05

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER